

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration Seattle District Pacific Region 22201 23rd Drive SE Bothell. WA 98021-4421

Telephone: 425-486-8788 FAX: 425-483-4996

June 6, 2001

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Dale E. Wickum, Owner Superior Feeds 114 E. Washington Chester, Montana 59522

In reply refer to Warning Letter SEA 01-57

WARNING LETTER

Dear Mr. Wickum:

An inspection of your animal feed manufacturing operation located at Chester, Montana, conducted by a Food and Drug Administration (FDA) investigator on April 25, 2001, found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 - Animal Proteins Prohibited in Ruminant Feed. The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and/or distributed by this facility to be misbranded within the meaning of Section 403(f) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found a failure to label your product with the required cautionary statement "Do Not Feed to Cattle or Other Ruminants." In that your sequencing feeds, intended to clean out the equipment after producing a feed containing prohibited materials, were not labeled with the cautionary statement. The FDA suggests the statement be distinguished by different type size or color or other means of highlighting the statement so that it is easily noticed by a purchaser.

The above is not intended to be an all-inclusive list of deviations from the regulations. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulation.

Dale E. Wickum, Owner Superior Feeds, Chester, Montana Re: Warning Letter # SEA 01-57

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You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations, and prevent their recurrence. If corrective action cannot be completed in 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer. If you have any questions please contact Mr. Williamson at (425) 483-4976.

Sincerely,

Charles M. Breen District Director

Enclosure:

Form FDA 483

Small Entity Compliance Guide